

### REMARKS

Claims 1-62 are pending in the application. Claims 6, 9-11, 13, 14, 23-27, 29, 34-36, 39-42, 44-56 and 62 have been allowed. Claims 1-5, 7, 8, 12, 15-22, 28, 30-33, 37, 38, 43 and 57-61 have been rejected.

Claims 1, 30, 43, 57, 58 and 59 have been amended such that the device generates a warning signal in response to the detection of light when the door is open so as to prevent it from operating further unless a source of light from outside of the housing is absent. Claims 2-5, 7, 8, 12, 15-22, 31-33, 37, 38 and 58-61 which depend upon these Claims also incorporate these limitations. Support for this is found in paragraph 0066 in the specification. The device will not operate even if a small hole is formed in the lid which lets in light. As described in paragraph 0055 of the specification, initially the LED is on and the signals from the photodiodes 14 and 16 are integrated, digitized and inputted in the microprocessor 34 where a resulting signal  $L_1 = L_s - L_r$  is measured. If the resulting signal exceeds a level above the expected LED intensity range at 56, which is equal to  $NL_{led}$ , wherein  $L_{led}$  is the stored LED reference value, a high-ATP sample is indicated. As taught in paragraph 0066, upon the first detection of light coming through the hole, the device will read a

signal as the one emitted by a high-ATP sample. However, during the next measurement indicating the high-ATP sample, the device will warn a user to check if the lid is damaged.

Claim 28 has been amended such that the transparent window is covered with an electro-conductive plastic and a filter which is a bandpass or a band-limited filter. Support for the bandpass filter is found in paragraph 0069 and 0071 of the specification. Support for the band limited filter is found in paragraph 0071 of the specification.

***Claim Rejections- 35 U.S.C. §112***

1. Claims 1-5, 7, 8, 12, 15-22, 57, 60 and 61 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The limitation directed to a sensor for generating a door signal indicative of a closed door has been removed from the claims. The amended claims are directed to software which determines the presence of light from outside the housing as supported on page 16, paragraph 0066 of the specification. The software operates such that the device will generate a warning signal in response to the detection of light when the door is open and not operate further if even a small hole is formed in the lid

which allows in light. Upon the first detection of light coming from outside of the housing the device will read a signal as the one emitted by a high-ATP sample. However, during the next measurement indicating the high-ATP sample due to the presence of light from outside the housing, the device will warn a user to check if the lid is damaged. In light of these amendments, the subject matter of Claims 1-5, 7, 8, 12, 15-22, 57, 60 and 61 is described in the specification in such a way as to comply with the written description requirement. Reconsideration of the rejection is requested.

***Claim Rejections- 35 U.S.C. §103***

2. Claims 1, 7, 12, 43, 57 and 61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Silver et al. (U.S. Patent No. 6,372,511) in view of Wright et al. (WO 00/70011).

Silver et al. teach a hand-holdable self-contained luminometer for use in detecting and quantifying low levels of luminescent emissions. Silver et al. do not teach a hand-held assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing.

Wright et al. teaches an apparatus for testing a biological fluid from an animal for the presence of disease in the animal. The apparatus including a container, a dipstick and a luminometer. The luminometer receives the container and is operated whereby a determination of the level of bacteria in the sample and hence of disease in the animal is made, by sensing the light emissions from the container. Wright et al. do not teach a hand-held assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing.

Claims 1 and 57 have been amended to include software executed on the controller which generates a warning signal in response to the detection of light when the door is open. Claim 43 has been amended such that the controller prevents the device from operating further unless a source of light from outside of the housing is absent. Claims 7, 12 and 61 depend from these claims and incorporate the limitations. Silver et al. and Wright et al. do not show or suggest these limitations. In light of these amendments, Claims 1, 7, 12, 43, 57 and 61 are patentable over the prior art. Reconsideration of the rejection is requested.

3. Claims 2-5, 22, 33, 38, 59 and 60 were rejected under 35 U.S.C. §103(a) as being unpatentable over Silver et al. (U.S. Patent No. 6,372,511) in view of Wright et al. (WO 00/70011) further in view of Taylor et al. (U.S. Patent No. 6,187,267) and Bryan (U.S. Patent No. 6,458,547) and Anderson et al. (U.S. Patent No. 4,818,883).

Claim 1 has been amended to include software executed on the controller which generates a warning signal in response to the detection of light when the door is open. Claims 2-5, 22 each depend from Claim 1, so as to incorporate this limitation. Claim 30 has been amended to incorporate software executed on the controller which prevents the device from operating further unless the reference signal is below a threshold suggesting that light from outside of the housing is absent. Claims 33 and 38 depend upon Claim 30 and so incorporate these limitations. Claim 59 is directed to a method amended to only continue the detection procedure if a resulting signal generated does not exceed a level expected when there is an absence of a source of light from outside of the housing.

Silver et al. and Wright et al. were discussed previously. Taylor et al. teach a device for detecting chemiluminescence having a stage for supporting a sample and one or more of the following elements: (1) an optics

head, (2) an optical relay structure for transmitting chemiluminescence from the sample to a detector, (3) a drive mechanism, (4) a sensor for detecting proximity of the optical relay structure to the sample, (5) a mask structure for selecting an effective diameter of the optical relay structure, and (6) a baffle for blocking extraneous light from entering the optical relay structure. Taylor et al. do not teach a hand-held assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing..

Bryan teaches solid phase methods for the identification of an analyte in a biological medium, such as a body fluid, using bioluminescence. Bryan teaches a chip designed for identification of an analyte and detecting bioluminescence, methods employing biomineralization for depositing silicon on a matrix support, and a synthetic synapse. Bryan does not teach a hand-held assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing.

Anderson et al. teach a luminometer apparatus has a light-tight box into which a cuvette containing a sample and a reagent are located for producing a phosphorescent

reaction. The phosphorescent reaction is detected by a photodetector and a shutter is interposed between the cuvette and the shutter. Output signals from the photodetector are applied to a circuit arrangement which detects the phosphorescent reaction at predetermined intervals and by subtracting the successive values of light from one another so a measured peak value of light intensity is determined. The shutter is closed and the dark current signal of the photodetector is determined and subtracted from the measured peak value. Anderson et al. do not teach a hand-held assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing.

Neither Silver et al., Wright et al., Taylor et al., Bryan or Anderson et al. show or suggest the limitations of the amended claims. In light of these amendments, Claims 2-5, 22, 33, 38, 59 and 60 are patentable over the prior art. Reconsideration of the rejection is requested.

4. Claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Silver et al. (U.S. Patent No. 6,372,511) in view of Wright et al. (WO 00/70011) further in view of Wood (U.S. Patent No. 5,650,289).

Claim 8 depends upon Claim 1, and so incorporates the new limitations of this claim. Silver et al. and Wright et al. were discussed previously. Wood teaches methods and compositions for improved kinetics of beetle luciferase-luciferin reactions for assaying samples for the presence of ATP. The invention also provides the complex of the coenzyme, Coenzyme A, a beetle luciferase and oxyluciferin in its excited state in the luciferase-luciferin reaction and luciferyl-CoA, the thioester of Coenzyme A and luciferin (D-(-)-2-(6'-hydroxy-2'-benzothiazolyl)- $\Delta^2$ -thiazoline-4-carboxylic acid). Neither Silver et al. and Wright et al., or Wood show or suggest a hand-held assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing. In light of these amendments, Claim 8 is patentable over the prior art. Reconsideration of the rejection is requested.

5. Claims 15 was rejected under 35 U.S.C. §103(a) as being unpatentable over Silver et al. (U.S. Patent No. 6,372,511) in view of Wright et al. (WO 00/70011).

Claim 8 depends upon Claim 1, and so incorporates the new limitations of this claim. Silver et al. and Wright et



al. were discussed previously. Silver et al. and Wright et al., either taken alone or in combination do not show or suggest a hand-held assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing. In light of these amendments, Claim 15 is patentable over the prior art. Reconsideration of the rejection is requested.

6. Claims 16-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Silver et al. (U.S. Patent No. 6,372,511) in view of Wright et al. (WO 00/70011) and further in view of Ghaed et al. (U.S. Patent No. 5,700,427).

Claims 16-21 also depend upon Claim 1, and so incorporate the new limitations of this claim. Silver et al. and Wright et al. were discussed previously. Ghaed et al. teach an apparatus for carrying out electrochemiluminescent measurements which includes a working electrode and a temperature sensor. The electrochemiluminescent measurements made by the apparatus are adjusted based upon the measured temperature. Ghaed et al., either taken alone or in combination with Silver et al. and Wright et al., do not show or suggest a hand-held

assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing. In light of these amendments, the Claims 16-21 are patentable over the prior art. Reconsideration of the rejection is requested.

7. Claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over Silver et al. (U.S. Patent No. 6,372,511) in view of Taylor et al. (U.S. Patent No. 6,187,267).

Claim 28 has been amended such that the transparent window is covered with an electro-conductive plastic and a filter which is a bandpass or a band-limited filter. Silver et al. and Taylor et al. have been discussed previously. Neither Silver et al. and Taylor et al., either taken alone or in combination, teach a transparent window which is covered with both an electro-conductive plastic and a filter which is a bandpass or a band-limited filter. In light of these amendments, the Claim 28 is patentable over the prior art. Reconsideration of the rejection is requested.

8. Claims 30, 32, 37 and 58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Silver et al. (U.S. Patent No. 6,372,511) in view of Wright et al. (WO 00/70011).

Claim 30 has been amended to incorporate software executed on the controller which prevents the device from operating further unless the reference signal is below a threshold suggesting that light from outside of the housing is absent. Claims 32 and 37 depend upon Claim 30 and so incorporate these limitations. Claim 58 is directed to a method amended to only continue the detection procedure if a resulting signal generated does not exceed a level expected when there is an absence of a source of light from outside of the housing.

Silver et al. and Wright et al. were discussed previously. Silver et al. and Wright et al., either taken alone or in combination do not show or suggest a hand-held assay device wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing, or a method for detecting the presence of a sample which is only continued if a resulting signal generated does not exceed a level expected when there is an absence of a source of light from outside of the housing. In light of these amendments, Claim 30, 32,

37 and 58 are patentable over the prior art.  
Reconsideration of the rejection is requested.

9. Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Silver et al. (U.S. Patent No. 6,372,511) in view of Wright et al. (WO 00/70011) further in view of Liljestrand et al. (U.S. Patent No. 6,200,531).

Claim 30 has been amended to incorporate software executed on the controller which prevents the device from operating further unless the reference signal is below a threshold suggesting that light from outside of the housing is absent. Claim 31 depends upon Claim 30 and so incorporate these limitations.

Silver et al. and Wright et al. were discussed previously. Liljestrand et al. teach an apparatus for electrochemiluminescence (ECL) measurements with an ECL chamber having a transparent window defining one wall of the chamber and a photodetector mounted closely adjacent to the window. An assay fluid is subjected to a magnetic field so as to electrically energized the fluid. Electrochemiluminescence induced in the fluid is measured by the photodetector. Liljestrand et al., either taken alone or in combination with Silver et al. and Wright et al., do not show or suggest a hand-held assay device

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wherein the device is prevented from operating further unless there is an absence of a source of light from outside of the housing. In light of these amendments, Claim 31 is patentable over the prior art. Reconsideration of the rejection is requested.

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The cited references in combination do not teach all of the elements of the present invention. Therefore, in light of the above, it is now believed that Claims 1-62 are patentable and in condition suitable for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

  
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